UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel. MICHAEL DAUGHERTY,	:	NO. 1:08-CV-00354
Plaintiff,	:	
	:	OPINION AND ORDER
v.	:	
BOSTWICK LABORATORIES, et al.	:	
Defendants.	:	

This matter is before the Court on Defendant Bostwick Laboratories' Motion to Dismiss (doc. 39), Defendant David Bostwick's Motion to Dismiss (doc. 56), and the respective responsive memoranda (docs. 44, 54, 59 & 61). For the following reasons, the Court DENIES each Motion to Dismiss (docs. 39 & 56).

I. Background

Relator filed his amended complaint in this qui tam action on February 13, 2012, alleging that Defendant Bostwick Laboratories (individually, the "Bostwick Lab") and Defendant David Bostwick (individually, "Mr. Bostwick" and, together with Bostwick Lab either "Defendants" or "Bostwick") (i) submitted false claims to Medicare, Medicaid and other federally-funded

programs for non-allowable lab services done without a physician's order and (ii) billed federally-funded healthcare programs for lab services unlawfully referred to Defendants in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), the Stark Laws, 42 U.S.C. § 1395nn, and the False Claims Act, 31 U.S.C. §§ 3729-3733 (doc. 34)(the "Act" or the "FCA"). The Government, as well as the states of Florida, Georgia, Indiana, New York, Tennessee, Texas, Virginia and the District of Columbia declined to intervene (doc. 18).

According to the allegations in the Amended Complaint, Relator is the president of LabMD, which is an Atlanta-based urology and uropathology laboratory and, in essence, a competitor of Defendant Bostwick Lab (doc. 34). Bostwick Lab provides laboratory and pathology services, including cytology interpretation services, and accepts specimens from referral sources throughout the United States (Id.). Nearly 87% of Bostwick Lab's 2007 revenue was from its urology business, 42.2% of its revenues were derived from Medicare and Medicaid, and approximately 35% of its revenues were from the evaluation of non-invasive bladder cancer tests, which are the tests implicated in this lawsuit.

Mr. Bostwick founded Bostwick Lab and is its Chief Executive Officer. Although Mr. Bostwick is no longer majority shareholder, Relator alleges that, since the company's

inception, Mr. Bostwick has controlled the actions of Bostwick Lab, and the actions constituting the fraud alleged by Relator were done at his direction and control.

Because Relator and Bostwick Lab provide some of the same services, they also share some of the same customers, and it is from some of these customers that Relator learned of some of the practices alleged in the amended complaint. In addition, Relator has personal familiarity with Bostwick Lab's procedures and personnel because for two years Bostwick Lab provided diagnostic testing on samples submitted to Relator's company's predecessor through a contract relationship between the two companies (Id.).

At base, Relator alleges (i) that Bostwick submitted claims for payment to the government for services that were not ordered by a physician and (ii) that Bostwick improperly incentivized physicians to provide Bostwick with business (Id.). The specific service at issue is called the Fluorescence In Situ Hybridization test (the "FISH test"), which is a test for bladder cancer. Typically, when concerned about the possibility of bladder cancer, urologists routinely order urine cytology, where a urine sample is sent to a lab and examined under a microscope to determine whether cancerous or precancerous cells are present (Id.). Should the urine cytology suggest that

malignant or atypical/suspicious cells are present in the urine, the American Urological Association's position is that cystoscopy is required, a procedure wherein the bladder and the urethra are examined using a thin, lighted instrument called a cytoscope (Id.). There are some FDA-approved non-invasive tests to assist in the diagnosis and surveillance of bladder cancers, and the FISH test is one of them. However, the FISH test is an adjunctive test, meaning that it received FDA approval for use "in conjunction with and not in lieu of current standard diagnostic procedures" to assist in the initial diagnosis of bladder cancer in patients with blood in the urine and in diagnosing recurrences in those patients with a history of bladder cancer (Id.). The American Urological Association does not include the FISH test as part of its Best Practices Policy Recommendations for the diagnosis of bladder cancer because, "insufficient data are available to recommend [its] use in the evaluation of patients with microscopic [blood in the urine]" (Id.).

The FISH test has two components to it: the technical component and the professional component. The technical component refers to the preparation of the sample and the addition of the fluorescent DNA probes to the specimen, which is then incubated. The professional component refers to the analysis of the sample after incubation and the interpretation

of the analysis. According to the FDA, this requires viewing the probe signals through filters on a microscope and analysis of specimen slides to determine whether abnormal or suspicious cells are present (Id.).

Relator alleges that Bostwick engaged in a scheme to defraud the government by reflexively conducting the FISH test without the ordering physician's consent and submitting the claim to Medicare and Medicaid and other federally-funded programs (Id.). Specifically, Relator notes that Bostwick's requisition form has a pre-printed list of choices for the ordering physician: (i) cytology; (ii) cytology/FISH; (iii) cytology/reflex FISH, with a footnote that the lab will "reflex when results are atypical" (Id.). Relator alleges that Bostwick reflexively performs FISH tests on atypical urine cytology results, irrespective of the physician's order on the requisition form (Id.).

In addition, Relator alleges that Bostwick also performs additional tests regardless of whether they are necessary or whether they have been requisitioned by the ordering physician and bills those unnecessary tests to federal healthcare programs (Id.).[1]

[1] Further, Relator claims that Bostwick diluted the probes used for the FISH testing in contravention of the FDA label, which allowed Bostwick to bill federal healthcare programs for

With respect to his claim regarding impermissible referrals, Relator alleges, in essence, that Bostwick offers urology practices incentives to refer testing to Bostwick, in violation of the Stark Laws and the Anti-kickback Statute. Specifically, Relator alleges that Bostwick developed a program wherein Bostwick performs both the technical and the professional components of the FISH test but allows the urology practice to bill for the professional component. Allegedly, in exchange for getting all of certain types of lab work from urology practices, Bostwick performs the technical component of the FISH test and then drafts a report constituting the professional component, which the urology practice's pathologist or physician then signs and bills as though they conducted the professional component of the test.

As additional violations of the Stark Laws and the Anti-kickback Statute, Relator alleges that, in exchange for referrals, Bostwick charges physicians a lesser amount to perform the technical component of the FISH test, and the physicians then bill Medicare for a higher amount, thus profiting from the arrangement. Further, Relator alleges, inter alia, that Bostwick offers discounted billing for privately

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three additional FISH tests per probe at no additional cost (Id.). However, in his response to Bostwick's motion to dismiss, Relator moved to strike this allegation, and the Court will therefore not consider it.

insured patients in exchange for the practices referring federal healthcare program business to Bostwick; routinely waives co-pays and deductibles for Medicare patients; encourages customers to issue standing orders to reflex FISH and other tests that have high reimbursement rates; offers financial assistance with electronic medical records in exchange for referrals of business; offers to assist physician practices in establishing in-house laboratories by offering below-market services in exchange for referrals.

In Count I, Relator claims that Bostwick knowingly presented or caused to be presented to officers or employees of the United States false claims for payment or approval in violation of the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(A); knowingly made, used, or caused to be made or used, false records or statements material to claims paid or approved by the Government, in violation of 31 U.S.C. §§ 3729(a)(1)(B); and presented or caused to be presented false or fraudulent claims for payment to the United States for lab services provided pursuant to illegal referral arrangements, in violation of 42 U.S.C. § 1395nn(a) and 42 U.S.C. § 1320a-7b(b). As Relator notes, these distill to allegations that "Bostwick performed and billed for tests that were not ordered by the treating physician and so are not covered and payable by federal programs;

and…Bostwick offered and paid remuneration of various kinds to induce physicians to refer federal healthcare business in violation of the [Anti-Kickback Statute] and Stark laws" (doc. 44). Counts II-IX are similar state-law claims, brought under the laws of Texas, Georgia, Florida, Virginia, Tennessee, New York, the District of Columbia, and Indiana.

Bostwick Lab moves to dismiss Relator's complaint on both jurisdictional and substantive bases (doc. 39). As to the jurisdictional argument, Bostwick Lab contends that Relator's allegations regarding Bostwick's markup program for the technical component of the FISH test are barred under the public disclosure bar of the False Claims Act. With respect to the remainder of the complaint, Bostwick Lab argues that Relator has failed to state a claim for relief because reimbursement for FISH tests ordered by pathologists is not violative of the False Claims Act and because the complaint does not set forth facts that would support an inference that Bostwick provided remuneration to physicians in exchange for referrals. In addition, Bostwick Lab argues that the complaint fails to meet the heightened pleading requirements of Rule 9(b) because Relator has not identified any single allegedly false claim that was submitted to the government, let alone several examples from which a scheme could be inferred.

Pursuant to Federal Rule of Civil Procedure 12(b)(6),

Mr. Bostwick moves to dismiss Relator's complaint as against him on the basis that the complaint does not set forth facts from which the Court could reasonably pierce the corporate veil and hold him personally responsible for the acts of Bostwick Lab (doc. 56).

Both motions to dismiss are ripe for the Court's consideration, and the Court takes each in turn.

II. The Applicable Standards & the Statutory Framework

A. Jurisdiction

Rule 12(b)(1) of the Federal Rules of Civil Procedure provides that an action may be dismissed for "lack of subject-matter jurisdiction." Fed.R.Civ.P. 12(b)(1). Plaintiffs bear the burden of proving jurisdiction when challenged by a Rule 12(b)(1) motion. Moir v. Greater Cleveland Reg'l Transit Auth., 895 F.2d 266, 269 (6th Cir. 1990)(citing Rogers v. Stratton Indus., Inc., 798 F.2d 913, 915 (6th Cir. 1986)). "[T]he plaintiff must show that the complaint alleges a claim under federal law, and that the claim is substantial." Mich. S. R.R. Co. v. Branch & St. Joseph Counties Rail Users Ass'n, Inc., 287 F.3d 568, 573 (6th Cir. 2002) (internal quotations omitted) (quoting Musson Theatrical, Inc. v. Fed. Express Corp., 89 F.3d 1244, 1248 (6th Cir. 1996)). "The plaintiff will survive the motion to dismiss by showing 'any arguable basis in law' for the

claims set forth in the complaint." Id. (quoting Musson Theatrical, 89 F.3d at 1248).

B. Federal Rule of Civil Procedure 12(b)(6)

Typically, a motion to dismiss brought pursuant to Federal Rule of Civil Procedure 12(b)(6) requires the Court to determine whether a cognizable claim has been pled in the complaint. The basic federal pleading requirement is contained in Fed. R. Civ. P. 8(a), which requires that a pleading "contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." Westlake v. Lucas, 537 F.2d 857, 858 (6th Cir. 1976); Erickson v. Pardus, 551 U.S. 89 (2007). In its scrutiny of the complaint, the Court must construe all well-pleaded facts liberally in favor of the party opposing the motion. Scheuer v. Rhodes, 416 U.S. 232, 236 (1974). A complaint survives a motion to dismiss if it "contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Courie v. Alcoa Wheel & Forged Products, 577 F.3d 625, 629-30 (6th Cir. 2009), quoting Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009), citing Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007).

However, because the False Claims Act is an anti-fraud statute, complaints alleging violations of the Act must meet the heightened pleading standard of Federal Rule of Civil Procedure 9(b). U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d

493, 510 (6th Cir. 2007). Rule 9(b) of the Federal Rules governs all averments of fraud or mistake and mandates that the circumstances constituting the fraud or mistake be stated with particularity. Fed. R. Civ. P. 9(b). Thus, a complaint alleging violations of the False Claims Act must minimally include "the time, place, and content of the alleged misrepresentation…; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." Bledsoe, at 504 (internal quotations and citations omitted). In the context of a False Claims Act case, "pleading an actual false claim with particularity is an indispensable element of a complaint…." Id. However, a relator need not plead "every specific instance of fraud where [his] allegations encompass many allegedly false claims over a substantial period of time." Id. at 509. Instead, "where a relator pleads a complex and far-reaching fraudulent scheme with particularity, and provides examples of specific false claims submitted to the government pursuant to that scheme, a relator may proceed to discovery on the entire fraudulent scheme." Id. at 510.

C. The False Claims Act

Congress passed the original False Claims Act in 1863 "to combat rampant fraud in Civil War defense contracts." S. Rep. No. 99-345, at 8, reprinted in 1986 U.S.C.C.A.N. 5266, 5273

(1986). In its current form, the FCA imposes liability on any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States government…a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(2008). The statute further imposes liability on a person who "uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government;" who "conspires to defraud the government by getting a false or fraudulent claim paid or approved by the government," or who uses "a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government." Id. at (a)(2),(3),(7). To satisfy the statute's knowledge requirement, a person must "(1) ha[ve] actual knowledge of the information; (2) act in deliberate ignorance of the truth or falsity of the information; (3) or act in reckless disregard of the truth or falsity of the information," but "no specific intent to defraud is required." Id. § 3729(b).

Relator must further demonstrate that the underlying violation is material by proving that the government would not have paid the claim for reimbursement had it known about the underlying violation of the law. United States ex rel. Luckey v. Baxter Healthcare Corp., 183 F.3d 730, 732-33 (7th Cir. 1999). A false certification of compliance with the Anti-

Kickback Statute and Stark Statute in a Medicare cost report is actionable under the FCA. United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997). False claims to Medicare, including Medicare cost reports (CMS-2552's) and claims for payment, (UB-92's) (also known as form HCFA-1450), are actionable under the FCA. Id. The submission of UB-92's in violation of the Stark Statute constitutes a violation of the FCA, United States ex rel. Pogue v. Diabetes Treatment Centers of America, 238 F. Supp.2d 258, 266 (D.D.C. 2002), and compliance with the Anti-Kickback Statute is a condition of payment by the Medicaid program. 42 U.S.C. § 1320a-7b(b); United States ex rel. Barrett v. Columbia/HCA Healthcare Corp. 251 F. Supp.2d 28, 32 (D.D.C. 2003). Similarly, when a physician submits claims for payments (CMS-1500's), the physician impliedly certifies that the claim and the underlying transaction comply with the Anti-Kickback Statute. United States of America ex rel. Thomas v. Bailey, No. 4:06-CV-00465, 2008 U.S. Dist. LEXIS 91221, *39, (E.D. Ark. November 6, 2008).

The FCA does not create a private cause of action, but permits a person, designated a "Relator" to bring a civil action "for the person and for the United States government…in the name of the government." 31 U.S.C. § 3730(b).

The Supreme Court has affirmed an aggressive reading of the FCA, explaining that "Congress wrote expansively, meaning to 'reach all types of fraud, without qualification, that might result in financial loss to the government.'" Cook County, Ill. V. United States ex rel. Chandler, 538 U.S. 119 (2003)(quoting United States v. Neifert-White Co., 390 U.S. 228, 232 (1968)).

D. The Anti-Kickback Statute

The Anti-Kickback Statute prohibits any person or entity from offering, making or accepting payment to induce or reward any person for referring, recommending or arranging for federally funded medical services, including services provided under the Medicare and Medicaid programs:

> (b) Illegal remunerations.
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind --
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or

> rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> 42 U.S.C. § 1320a-7b(b).

The statute includes no requirement of proof that a kickback arrangement harmed patients or resulted in unnecessary procedures and it imposes liability for payment practices that do not fall within "Safe Harbor" regulations, 42 C.F.R. § 1001.952, so as to remove financial incentives that can result in unnecessary patient care.

E. The Stark Laws

The Stark Laws prohibit healthcare entities from submitting Medicare claims for payment based on patient referrals from physicians having a "financial relationship" with the entity. 42 U.S.C. § 1395nn. The provisions define a financial relationship as one where the physician has a direct

or indirect compensation relationship with the entity. 42 U.S.C. § 1395nn(a)(2)(A); 42 C.F.R. §411.354(a)(1). This includes any arrangement whereby a physician receives either direct or indirect remuneration from the entity. 42 C.F.R. §411.353(c).

III. Bostwick Lab's Motion to Dismiss

A. Relator's Markup Program Allegations are not jurisdictionally barred

Bostwick Lab argues that Relator's allegations regarding a markup program are jurisdictionally barred because the question of whether physicians could permissibly mark up the technical component of lab tests has been debated publicly for years (doc. 39). As Bostwick Lab notes, if a relator's claims are based on allegations or transactions that were publicly disclosed in certain sources, the public-disclosure bar requires dismissal of the suit (Id., citing 31 U.S.C. §3730(e)(4)(A)). As support for its contention that the markup program was publicly disclosed before Relator filed his complaint, Bostwick Lab points to the following. First, as Relator set forth in his complaint, Bostwick's General Counsel sent a letter to urology practices in April 2009 advising them of the markup program, wherein physicians could purchase the technical component of certain tests at a below-rate charge and then bill Medicare for

the full amount (Id.). In that letter, the General Counsel expressed his opinion that a regulatory loophole allowed Bostwick to do this because, he believed, the anti-markup rule was inapplicable to lab tests that don't require physician supervision (Id.). Second, Bostwick Lab notes that in June 2009 the American Society for Clinical Pathology, the American Clinical Laboratory Association, the College of American Pathologists and some large independent labs met with officials from the Centers for Medicare & Medicaid Services ("CMS") to discuss this loophole concept and the anti-markup rule (Id.). Bostwick Lab argues that this June 2009 meeting constitutes public disclosure under the applicable statute (Id., citing 31 U.S.C. §3730(e)(4)(A); U.S. ex rel. Ondis v. City of Woonsocket, 587 F.3d 49, 55 (1st Cir. 2009)). In addition, Bostwick Lab directs the Court to several articles discussing the loophole and the anti-markup rule, which were published before Relator filed his complaint. Further, Bostwick Lab notes that the College of American Pathologists wrote a letter to CMS in response to an opportunity to comment on a proposed rule. Because the letter was published on the CMS website, Bostwick Lab argues that it constitutes a public contribution to a federal proceeding and, therefore, a public disclosure under the False Claims Act (Id.).

The jurisdictional bar of the FCA provides:

> (4) (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing the action under this section which is based on the information. 31 U.S.C. § 3730(e)(4)(A) and (B).

To ascertain whether the application of the jurisdictional bar is appropriate, the Court must assess: "(A) whether there has been a public disclosure in a criminal, civil or administrative hearing; or congressional, administrative, or government report, hearing, audit, or investigation; or from the news media; (B) of the allegations or transactions that form the basis of the relator's complaint; and (C) whether the relator's action is 'based upon' the publicly disclosed allegations or transactions." United States ex rel. Jones v. Horizon Healthcare Corporation, 160 F.3d 326, 330 (6th Cir. 1998). Further, "[i]f the answer is 'no' to any of these questions, the inquiry ends and the qui tam action may proceed. If the answer to each of the

above questions is 'yes,' then the final inquiry is (D) whether the relator qualifies as an 'original source' under § 3730(e)(4)(B), which also would allow the suit to proceed." Id.

Applying that analysis to this case, the Court finds that the jurisdictional bar of the FCA does not apply to the allegations of a markup program because "substantial identity" between the disclosures and the complaint does not exist. See Horizon Healthcare, 160 F.3d at 332. With respect to the question of whether there was a public disclosure, as Relator notes, the letter sent by Bostwick's general counsel to its clients does not fall within the ambit of a public disclosure because it cannot legitimately be seen to be a criminal, civil or administrative hearing, a congressional, administrative or GAO report, hearing, audit or investigation, or from the news media. However, the articles to which Bostwick Lab refers are legitimate examples of "news media," and the CMS meeting and the letter to CMS in response to a solicitation for comments arguably are disclosures made in connection with administrative hearings; thus these disclosures fall within those certain forums enumerated in the statute. See, e.g., A-1 Ambulance Serv., Inc. v. California, 202 F.3d 1238, 1243-44 (9th Cir. 2000)(county public agency proceedings are "administrative hearings" under FCA); United States ex rel. Englund v. Los

Angeles County, 2005 WL 2089216 (E.D. Cal. 2005)(letters generated in connection with public board meetings fall within public disclosure definition).

The questions then become whether the disclosures made in those fora included the allegations or transactions that form the basis of the complaint and whether the complaint is "based upon" the publicly disclosed allegations or transactions. Simply put, they do not: as Relator notes, the disclosures did not contain enough information to expose the fraudulent transactions in their entirety because they did not identify Bostwick specifically, and they did not discuss the incentives provided by Bostwick.

The Sixth Circuit has relied on an illustration set forth by the D.C. Circuit to determine whether the public disclosure bar should apply:

> I]f X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed. [Q]ui tam actions are barred only when enough information exists in the public domain to expose the fraudulent transaction (the combination of X and Y), or the allegation of fraud (Z).

U.S. ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503, 513 n. 5 (6th Cir. 2009), quoting United States ex rel. Springfield

Terminal Ry. v. Quinn, 14 F.3d 645, 654 (D.C. Cir. 1994). Here, as Relator notes, the allegations set forth in the amended complaint are that Bostwick employed a scheme whereby it would markup the technical component of tests in order to induce physician practices to refer business its way, and the transactions include Bostwick's offering these incentives to physician practices by way of its marketing and solicitations, which allegedly resulted in claims paid in violation of the AKS and the Stark Laws. The public disclosures presented by Bostwick Lab do not marry these allegations and transactions such that the government could readily ascertain that X+Y=Z. Instead, the disclosures focus on the reach of the anti-markup rule, not the particulars of the fraud alleged here or, importantly, the Defendants served here.

This is not merely an issue of "re-characterizing material elements already in the public domain as a false claim," as Bostwick Lab contends (doc. 54). Instead, Bostwick Lab simply has not provided a source of publicly-disclosed information that either details the elements of the allegedly fraudulent transactions (the X+Y) or the fraud itself (the Z). There is no "re-characterization" where the material elements are not already in the public domain.

Finally, if the Court is wrong in its assessment

regarding the lack of a public disclosure, the Court finds that Relator's complaint is not "based upon" those disclosures. In this Circuit, to determine whether a complaint is based on public disclosures, courts look to whether "'substantial identity' exists between the publicly disclosed allegations or transactions and the…complaint." U.S. ex rel. McKenzie v. BellSouth Telecommunications, Inc., 123 F.3d 935, 940 (6th Cir. 1997)(internal quotations and citations omitted). Here, such identity does not exist. On this issue, the Court appreciates Relator's analogy: "A handbook describing how to crack a safe does not mean that the fact that a particular safecracker robs banks is publicly disclosed" (doc. 44).

Relator's complaint is not barred by the public disclosure bar.

B. Relator has Stated a Claim for Relief

1. The Fraudulent Billing Scheme

In essence, Relator's claim that Bostwick fraudulently billed federal healthcare programs amounts to an allegation that Bostwick performed and billed for and received payment for FISH tests that were not ordered by the treating physician and so are not covered and payable by federal programs.

Bostwick Lab argues that Relator fails to set forth a claim for relief in his complaint because, it contends, Relator

does not present even a single case of a medically unnecessary FISH test having been billed to federal healthcare programs by Bostwick (doc. 39). Specifically, Bostwick Lab contends that any FISH test it ran without a treating-physician signature was medically necessary in order to allow the pathologist to reach a diagnosis, which is an exception to the rule that all tests paid for by federal healthcare programs must be ordered by the treating physician (Id., citing Medicare Benefit Policy Manual, Ch. 15, § 80.6.5). The exception provides that an independent laboratory's pathologist may order additional tests in the absence of a treating-physician order if the test is needed to allow the pathologist to report a "complete and accurate diagnosis" to the treating physician (Id.). Bostwick Lab contends that Relator has failed to allege a single instance where it billed for a test that doesn't fit within that exception and therefore urges the Court to dismiss the complaint.

Relator argues that Bostwick Lab's motion to dismiss challenges Relator's factual allegations and does not, as it should, test Relator's cause of action. Relator is correct. At this stage, the Court must accept as true the factual allegations contained in the complaint and assess whether or not those allegations state a plausible claim. They do. Relator

alleges that Bostwick performed FISH tests on specimens where they were not ordered, despite the presence on the requisition form for the treating physician to order the test or to allow for testing only when the initial cytology was abnormal. In addition, Relator alleges that these non-physician-ordered FISH tests were done with no notice to the physicians and automatically as a matter of course not on a patient-by-patient basis.

Tests billed without a physician's order under the circumstances alleged in the complaint could plausibly be found to be medically unnecessary and thus fraudulent under the FCA, and that is the only question before the Court at this stage. Through the discovery process, it will become clearer whether and to what extent the pathologist exception to the rule that tests must be ordered by the treating physician might apply to the any, all or none of the allegedly fraudulent claims. To illustrate, in order for the exception that allows pathologists to bill for tests absent a physician order to apply, three factors must be present: the services must be medically necessary so that a complete and accurate diagnosis can be reported to the treating physician/practitioner; the results of the tests must be communicated to and be used by the treating physician/practitioner in the treatment of the beneficiary; and

the pathologist must document in his/her report why additional testing was done. Medicare Benefit Policy Manual Chapter 15 §§ 80.6.5. Relator alleges that Bostwick routinely performed unordered FISH tests as a matter of business policy without any individual assessment as to the needs of the particular patient. In its briefing, Bostwick Lab contends that it only ordered FISH testing when the particular patient's situation required it and that it gave notice to the treating physician. This is a factual dispute not suitable to resolution on a motion to dismiss.

For the foregoing reasons, the Court finds that Relator has set forth sufficient factual allegations from which the Court may plausibly infer a fraudulent billing scheme conducted by Bostwick.

2. The Impermissible Kickbacks

In addition to his claim that Bostwick Lab engaged in a fraudulent billing scheme, Relator alleges that Bostwick Lab provided remuneration to physicians in order to induce them to refer business its way in violation of the Anti-Kickback Statute and the Stark Laws. Bostwick Lab urges the Court to dismiss this portion of Relator's complaint, arguing that he has failed to state a claim for relief because he did not provide facts from which the Court could infer that Bostwick Lab falsely

certified that it was in compliance with the AKS or Stark Laws in connection with actual claims submitted to federal healthcare programs (doc. 39). Bostwick Lab contends that, in his complaint, Relator merely describes some of Bostwick's business programs but he has not provided any facts to support his legal conclusion that those programs are illegal or improper. Essentially, Bostwick Lab's arguments distill to two. First, Relator's allegation that Bostwick falsely impliedly certified compliance with the AKS fails as a matter of law because, it contends, an implied certification theory only applies where the underlying statute or regulation specifically states that compliance is a prerequisite to obtaining payment for a claim submitted to the government. Because there was no such statute or regulation that conditioned payment on compliance with the AKS, Bostwick Lab contends, there can be no implied certification. Second, Bostwick Lab argues that Relator's complaint must be dismissed because it fails to allege that Bostwick offered or gave remuneration to physicians in connection with referrals.

a. Certification

The Court is unpersuaded by Bostwick Lab's arguments regarding implied certification. First, as Relator notes, certification is not a separate element of an FCA claim. The

question is, instead, whether Bostwick knowingly submitted false claims in violation of a material condition of payment. See, e.g., U.S. ex rel. Hutcheson v. Blackstone Medical, Inc., 647 F.3d 377 (1st Cir. 2011). Relator has alleged facts which, accepted as true, plausibly allow an inference that it did.

As part of its application to participate in the federal healthcare programs, Bostwick signed a supplier agreement. As alleged in the amended complaint, that agreement contains a certification that reads in relevant part, "I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law)" (doc. 34). As Bostwick Lab notes, the Sixth Circuit has not decided whether an alleged violation of this certification can serve as the basis for an FCA claim, and the Court need not make that determination as a matter of law in order to reach its decision. This certification, while a part of the application to participate in the federal healthcare programs, speaks directly and expressly to payment of claims and reinforces the materiality of compliance with the AKS and the Stark Laws to the government's willingness to pay suppliers. With its signature, Bostwick certified to the government that the claims it would

submit would comport with, inter alia, the AKS and the Stark Laws.

In addition, as this Court has previously determined, violations of the AKS and Stark Laws are material as a matter of law. U.S. ex rel. Fry v. The Health Alliance of Greater Cincinnati, 2008 WL 5282139, *33 (S.D. Ohio, Dec. 18, 2008). It is not a large leap at all to conclude that compliance with the AKS and the Stark Laws would have a natural tendency to influence the federal government's decision to pay a claim. See, e.g., United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc., 400 F.3d 428, 445 (6th Cir. 2005). Stated differently, had the government known about the referral-inducement programs alleged in the amended complaint, the government may very well have rejected payment of claims tainted by those programs. See, e.g., Ab-Tech Construction, Inc. v. United States, 31 Fed. Cl. 429, 434 (1994)(where the government pays money that it would not have paid had it known of a violation of a law or regulation, the claim submitted for that payment contains an implied certification of compliance with the law or regulation and is fraudulent). As in Fry, this case does not present a question of "compliance with regulations setting out conditions for participation in the Medicare program, but involve[s] certification of compliance with the Anti-Kickback

Statute, a condition of government payment." Fry, 2008 WL 5282139 at *12.

Relator has sufficiently alleged that Bostwick violated the AKS and the Stark Laws, and compliance with those statutes is a condition of payment from the government, placing Relator's complaint within the ambit of the FCA.

b. Remuneration

As the parties note, in order to state a claim based on an Anti-Kickback Statute violation, Relator must allege facts that support an inference that Bostwick (i)knowingly and willfully (ii) solicited or received, or offered or paid remuneration (iii) in return for, or to induce, referral or program-related business. See 42 U.S.C. § 1320a-7b. Under the Stark Laws, Relator must allege facts that support an inference that a physician had a "compensation arrangement" with Bostwick, where the physician received either direct or indirect remuneration from Bostwick. See 42 U.S.C. § 1395nn(a)(2); 42 U.S.C. § 1395nn(h)(1)(A); 42 CFR § 411.354(c). "Remuneration" for these purposes is broadly defined as "anything of value." See, *e.g.*, Fry, 2008 WL 5282139. At base, then, the question before the Court is whether Relator sufficiently alleged facts from which the Court could plausibly infer that Bostwick offered or provided something of value to physician practices in

exchange for referrals back from those practices. He did.

Specifically, Relator alleges that Bostwick offered physicians the opportunity to bill for the professional component of tests that the physicians did not perform in order to induce the physicians to refer testing to Bostwick (doc. 34). For example, Relator alleges that Bostwick offered to provide professional interpretation, with a complete analysis and a draft report with the physician practice's logo and a place for the physician signature. This would enable the physician to have the results of the professional component of the test without the physician having to actually conduct any professional analysis or incur any of the costs associated with performing the professional component of the test. To drive this inducement home, Bostwick assured physicians that "[t]here is no need to purchase a microscope, or anything else for that matter" (Id.). Such an arrangement, where Bostwick incurs all costs associated with the tests but where the physician practice gets to reap the payment from the federal healthcare program, is, to this Court, clearly an arrangement whereby something of value was given in order to induce referrals, exactly the scenarios contemplated by the AKS and the Stark Laws. Simply put, not having to do the work of the professional component of the test and not having to set up and maintain the

infrastructure in order to do the test and, instead, merely reviewing work that is already complete and signing one's name is certainly something of value. Bostwick Lab's contention that it is merely a "legitimate business practice" is a legal conclusion with which, at this stage in the proceedings at least, this Court disagrees.

Similarly, the Court finds that Relator's amended complaint satisfies the 12(b)(6) standard with respect to (i) the allegations that Bostwick induced physician referrals by offering physicians the opportunity to bill the technical components of certain tests at a marked-up price; and (ii) the allegations that Bostwick offered discounts on private insurance business in exchange for referrals of federal healthcare business. The amended complaint contains allegations that, in exchange for referrals to its lab, Bostwick offered physician practices the opportunity to bill federal healthcare programs for the technical components of, e.g., FISH tests, for which Bostwick would charge the practices at a discounted rate. And the amended complaint further alleges that Bostwick offered discounted rates on services provided to privately insured patients in exchange for referrals of patients with federal insurance. These allegations suffice to state a claim and thus allow the amended complaint to survive the motion to dismiss.

The Court notes that Bostwick Lab's arguments with respect to Relator's allegations regarding the markup and discount programs gave the Court pause. However, many of the cases to which Bostwick Lab cites for support were decided at the summary judgment stage. It may well be that, after discovery and on a full record, no liability on this point obtains. But the only question before the Court right now is whether Relator's amended complaint adequately states a claim, and it does.

C. Plaintiff's Complaint Meets the Heightened Pleading Standards of Rule 9(b)

"[T]he purpose undergirding the particularity requirement of Rule 9(b) is to provide a defendant fair notice of the substance of a plaintiff's claim in order that the defendant may prepare a responsive pleading." Michaels Building Co. v. Ameritrust Co., N.A., 848 F.2d 674, 679 (6th Cir. 1988). Relator must have alleged in his amended complaint the time, place and content of the misrepresentation; the fraudulent scheme; Bostwick's fraudulent intent; and the resultant injury. See U.S. ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503, 518 (6th Cir. 2009).

Relator's amended complaint adequately puts Bostwick on notices of the substance of his claim and sets forth

allegations supporting the fraudulent scheme, Bostwick's fraudulent intent, and the resultant injury. Bostwick Lab contends that the amended complaint is nonetheless deficient because Relator has not provided fraudulent claims actually submitted for payment. Given Relator's outsider status, the full panoply of claims submitted to the government by Bostwick for payment is only available through discovery. However, he did allege a representative example of what he claims is the impermissible reflex FISH testing: he identified a Florida urology practice that had not ordered or consented to a FISH test but for whom it was nonetheless done for a specific patient on a specific date. He further alleged that a Bostwick representative admitted that it was company policy to conduct reflex FISH testing without a physician's order. In addition, Relator points to instances involving physician practices in Georgia. As to the allegations of kickbacks, Relator not only relies on Bostwick's own marketing materials but also provides specific examples of the inducements made to practices, which are identified in the complaint by date and location.

The failure to attach actual fraudulent claims to the complaint is not fatal to Relator's case. The purposes of Rule 9(b) are amply satisfied with the allegations Relator sets forth. Taking the allegations as a whole and accepting them as

true, the Court draws a strong inference that false claims were submitted to the government as a result of the schemes described in the complaint. And having provided the requisite who, what, where, when, and how, Relator has complied with the dictates of Rule 9(b). Accord Fry, 2008 WL 5282139; U.S. ex rel. Repko v. Guthrie Clinic, 557 F. Supp.2d 522, 527 (M.D. Pa. 2008) ("attachment of some or all of the allegedly fraudulent claims would serve no further purpose consistent with Rule 9(b) because defendants are on notice that the basis of the alleged fraud in each claim is the relationship between the defendants, not anything unique to a particular claim, that has caused these claims to be allegedly fraudulent"); U.S. ex rel. McDonough v. Symphony Diagnostic Services, Inc., 2012 WL 628515 (S.D. Ohio, Feb. 27, 2012).

D. Conclusion

For the foregoing reasons, the Court DENIES Bostwick Lab's motion to dismiss (doc. 39).

IV. Mr. Bostwick's Motion to Dismiss

As an initial matter, Mr. Bostwick adopts and incorporates Bostwick Lab's motion to dismiss (doc. 56). Consequently, the Court's holdings with respect to that motion apply with equal force to Mr. Bostwick's motion. Thus, the Court will only address here those issues that are specific to

Mr. Bostwick as an individual defendant.

In essence, Mr. Bostwick argues that the Court should dismiss the complaint as against him because he is shielded by the corporate veil, and Relator has failed to show that the veil should be pierced (doc. 56). Relator contends that his complaint alleges that Mr. Bostwick, as an individual, committed fraud on the government, and he argues that, in addition, liability should attach to Mr. Bostwick because of his "inseparable identity" from Bostwick Lab in the commission (doc. 59).

Relator has the better end of this argument. He has adequately pled facts from which the Court can reasonably draw a plausible inference that Mr. Bostwick both personally participated in the fraud alleged in the amended complaint and that the fraudulent actions of Bostwick Lab can be imputed to him by virtue of the control he exerted over the company. Specifically, Relator has alleged that Mr. Bostwick controls the actions of the corporation to such a degree that the company has no separate mind from him and that Mr. Bostwick controlled and directed the allegedly fraudulent schemes carried out by the company (doc. 34). In addition to the well-pled allegations regarding the specifics schemes at issue here, these allegations are enough to withstand a motion to dismiss and to, at this

stage in the proceedings for the purposes of this motion, disregard the corporate form. See, e.g., Minno v. Pro-Fab, Inc., 121 Ohio St.3d 464, 467, 905 N.E. 2d 613 (Ohio 2009)(corporate form may be disregarded when the controlling individual and the corporation have no separate identity, control over the corporation was exercised to commit fraud or similarly unlawful act, and unjust loss resulted). Accepted as true, the allegations in the amended complaint create a scenario whereby Mr. Bostwick personally directed and benefitted from the alleged fraud, and he should not be permitted to hide behind a corporate form in order to perpetrate fraud. See, e.g., Dombroski v. WellPoint, Inc., 119 Ohio St. 3d 506, 510, 895 N.E.2d 538 (Ohio 2008); Flynn v. Greg Anthony Construction Co., Inc., 95 Fed.Appx. 726, 733-4 (6th Cir. 2003)(noting that when the corporation is merely an alter ego of its owners and has no separate identity, courts deal with the substance of the transaction as if the corporation did not exist, as justice may require).

As noted repeatedly, this is before the Court on a motion to dismiss. However, the extent to which an owner or director exercised control over a company is a fact question and thus not well-suited to answering definitively at this stage. It may be that through discovery it becomes clear that Mr.

Bostwick and Bostwick Lab did not have quite the merged identity that Relator alleges, but that is a question for another day and another motion.

Based on the record before the Court, the Court finds that Relator has sufficiently met his pleading burden as against Mr. Bostwick and thus DENIES the instant motion (doc. 56).

SO ORDERED.

Dated: December 14, 2012

s/S. Arthur Spiegel
S. Arthur Spiegel
United States Senior District Judge